



25 July 2024  
EMA/CHMP/SAWP/463927/2024  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 16-19 September 2024.

### Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures

	1995-2023	2024	Overall total
Scientific Advice	6072	295	6367
Follow-up to Scientific Advice	1928	112	2040
Protocol Assistance	1343	61	1404
Follow-up to Protocol Assistance	719	36	755
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	15	243
	10455	520	10974

### Outcome of the September 2024 CHMP meeting in relation to scientific advice procedures

#### Final scientific advice procedures

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
ATMP	Treatment of squamous cell carcinoma	x				x			
ATMP	Treatment of cancer			x				x	
ATMP	Treatment of cancer		x			x	x	x	x



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
ATMP	Treatment of Parkinson disease			x		x	x	x	
ATMP	Treatment of angioedema		x			x	x	x	x
ATMP	Treatment of pseudarthrosis		x					x	
Biological	Treatment of follicular lymphoma			x				x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of lung cancer	x				x			
Biological	Treatment of osteoporosis			x				x	
Biological	Treatment of cancer			x				x	
Biological	Prevention of cardiovascular event	x				x			
Biological	Treatment of lung cancer	x				x		x	
Biological	Treatment of allergy	x				x	x	x	
Biological	Treatment of tumours	x				x	x	x	
Biological	Treatment of lung cancer			x		x			
Biological	Treatment of NSCLC	x						x	
Biological	Treatment of multiple sclerosis	x				x		x	
Biological	Treatment of ovarian cancer				x	x			
Biological	Treatment of Atopic Dermatitis	x					x	x	
Biological	Treatment of lung cancer			x		x		x	
Biological	Treatment of lymphoma				x	x			
Biological	Treatment of rhinosinusitis	x						x	
Biological	Treatment of psoriasis			x				x	
Biological	Treatment of adenocarcinoma	x						x	
Biological	Treatment of kidney disease	x					x	x	
Biological	Treatment of Crohn's disease	x				x	x	x	
Biological	Treatment of multiple sclerosis			x		x		x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of thrombotic thrombocytopenic purpura		x			x			
Biological	Treatment of Friedreich's ataxia		x			x	x	x	
Biological	Treatment of asthma	x				x		x	
Biological	Treatment of multiple Myeloma	x						x	
Biological	Treatment of HNSCC	x						x	
Biological	Treatment of acquired factor X deficiency		x				x	x	
Biological	Treatment of peanut allergy	x				x		x	
Biological	Treatment of polyneuropathy			x				x	
Biological	Prevention of dementia	x						x	
Biological	Treatment of arthritis	x				x	x	x	
Biological	Prevention of herpes			x		x			
Biological	Treatment of cancer	x						x	
Biological	Treatment of eczema	x						x	
Biological	Treatment of mild cognitive impairment			x				x	
Biological	Prevention of influenza			x		x	x	x	
Biological	Prevention of influenza disease			x		x			
Chemical	Treatment of Dravet syndrome		x					x	x
Chemical	Treatment of hepatitis B			x		x			
Chemical	Treatment of NSCLC	x						x	
Chemical	Treatment of ADNP syndrome	x				x	x	x	
Chemical	Treatment of Amyotrophic lateral sclerosis	x				x	x		
Chemical	Treatment of chronic myeloid leukaemia				x			x	
Chemical	Treatment of multiple sclerosis			x				x	
Chemical	Treatment of biliary tract cancer				x			x	
Chemical	Treatment of chronic lymphocytic leukemia	x					x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of adenovirus infection				x		x	x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of Psoriasis			x		x			
Chemical	Treatment of cardiovascular disease	x				x		x	
Chemical	Treatment of AML	x				x		x	
Chemical	Treatment of Leber's congenital amaurosis				x			x	
Chemical	Treatment of carcinoma	x				x	x	x	
Chemical	Treatment of Hyperlipidaemia	x					x	x	
Chemical	Treatment of pain	x						x	
Chemical	Treatment of RSV disease			x				x	
Chemical	Prevention of cardiovascular disease	x				x			
Chemical	Treatment of Friedreich's ataxia				x			x	
Chemical	Treatment of cancer	x					x	x	
Chemical	Treatment of HIV-1 infection	x						x	
Chemical	Treatment of pulmonary fibrosis	x				x			
Chemical	Treatment of Ulcerative colitis	x				x	x	x	
Chemical	Treatment of weight disease			x		x		x	
Chemical	Treatment of kidney disease	x						x	
Chemical	Treatment of encephalopathy		x			x	x	x	
Chemical	Treatment of Dengue virus infection	x					x	x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 73 Scientific Advice letters – 39 Initial Scientific Advice, 19 Follow-up Scientific Advice, 8 Protocol Assistance letters, 7 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 16-19 September 2024.

## **New requests for scientific advice procedures**

The Committee accepted 74 new Requests for which the procedure started at the SAWP meeting held on 2-5 September 2024. The new requests are divided as follows: 47 Initial Scientific Advice, 17 Follow-up Scientific Advice, 8 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.